clarifying the claimed process and apparatus by inserting that the process involves several entities optionally remote including an operational entity and a preparation laboratory. This is supported by line 37 of page 2 through line 1 of page 3 and in lines 12 to 27 of page 5. In addition, the claim has been amended to indicate that after each functional stage, which is supported by lines 5 to 9 of page ,3 that there is a sequential and initial validation of each functional stage and also, at the end, there is a stage for inputting post reinjection follow up information and forwarding said information to the operational entity which is supported by lines 23 and 24 of page 6.

All of the claims stand rejected under 35 USC 103 as being obvious over the MDS Health Group Limited reference. The Examiner states that the MDS discloses functional steps of sequential and conditional validation as can be seen from Figs. 2 and 5 and the Examiner deems that any step in the flow chart in which a decision must made reads as a step of conditional validation . The Examiner states that the MDS differs from claim 1 only in not disclosing reinjecting cells but the Examiner takes official notice that it is well known to perform dialysis treatment where blood cells are removed from the body and subsequently reinjected. The Examiner deems it would have been obvious to modify the MDS to be used in the well known environment of a dialysis treatment.

With respect to Applicants' arguments relating to sequential and conditional validation for each functional stage, the Examiner finds in Figs. 2 and 5 the presence of decision points such as 215, 230, 240, 260 and 262 that are deemed sequential and conditional validation steps. With respect to Applicants' arguments concerning punctually or systematically follows by a validation stage, the Examiner deems that the claims do not make such requirement. In the Examiner's opinion, claims15 and 16 draw no separation between the functional stage and the validation stage and recite no sequence between the two. The Examiner states that the claims make no requirements on the number of operators that are needed or not needed to practice the invention.

Applicants respectfully traverse these grounds of rejection since it is believed that the present claims as modified, clearly distinguish from the MDS reference cited by the Examiner. MDS discloses an electronic worksheet system for microbiology testing and reporting comprising a work station coupled to a data base containing information relative to patients in a microbiology data base. This system provides with (i) assigning an identification number for accessing the data bases and for associating each tested sample with information relative to the concerned patient, (ii) collecting data relative to the tests carried out on the sample by means of screen pages and (iii) with delivering a report.

The MDS reference differs from the subject matter of modified claim 15 in that it 1) does not relate to a method for processing information used for quality management in a therapeutic process involving several entities, optionally remote, including an operational entity and a preparation laboratory. 2) It does not disclose, after each functional stage, the stage of sequential and conditional validation of said functional stage and 3) it does not disclose a stage for inputting post reinjection follow-up information and forwarding said information to the operational entity.

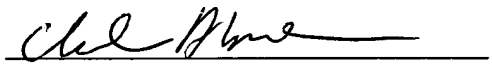
The MDS system is aimed at microbiology testing and reporting and not to quality management in a therapeutic process. Therefore, the MDS system does not require the same level of requirement and reliability and security as required for a method and system for processing information used for quality management in a therapeutic process that finally results in a critical operation of cell reinjection into a patient. In the microbiology testing reporting system disclosed in MDS, many of the functional stages such as for example, "input patient and specimen data into laboratory information system" or "scan test label to retrieve patient and specimen data" do not require to be systematically followed by a stage of sequential and conditional validation. This is because possible consequences of non-achievement or poor achievement of one or more of these functional stages is not critical and could be overcome which is not the case in Applicants' process. Moreover, when a response to a test (such as step 215 in Figure 2 or

steps 230, 244, 250, 254, 260, 262) is processed within the electronic worksheet of MDS. Whatever the result of the test may be, the work flow is not stopped as illustrated in the diagrams of Figures 2 and 5.

Moreover, MDS is not concerned with the problem of post injection follow up information since it only deals with microbiology testing and reporting but not with a therapeutic process. MDS would not teach or suggest to one skilled in the art of quality management in therapeutic processes, the principal of a stage of sequential and conditional validation, after each functional stage, the completion of which being a condition in passing from said functional stage to the following stage as recited in Applicants' claims. Therefore, the MDS does not render obvious Applicants' process and withdrawal of this ground of rejection is requested.

In view of the amendments to the claims and the above remarks, it is believed that the claims clearly point out Applicants' patentable contribution and favorable reconsideration of the application is requested.

Respectfully submitted,
Muserlian, Lucas and Mercanti



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CAM:ds
Enclosures

MARKED UP VERSION OF CLAIMS SHOWING CHANGES MADE

Claim 15 (amended) A method for processing information used for quality management in a therapeutic process involving several entities, optionally remote, including an operational entity and a preparation laboratory, this therapeutic process comprising operations of taking cells from a patient, specific treatment operations on these cells using a specific treatment protocol, and a reinjection operation into the patient of said cells treated in this way, these operations of taking cells, treatment and reinjection being subjected to a standard operating procedure for preparating procedure for preparation (SOP) comprising a series of functional stages,

Characterized in that it comprises, for each batch of samples taken from a given patient;

-[for] after each functional stage, a stage of sequential and conditional validation of said functional stage, passing from one validation state to a following validation stage being conditional on results of processing data collected during this validation stage and on a full completion by an operator of critical points within a screen page associated with said functional stage, [and]

-a stage of processing information and data collected in the different validation stages, said collected data being associated with said batch of samples and being in particular indicative of operators and of the process state of progress, in order to issue final certification of a preparation carrie8d out according to the standard operating procedure and/or a list of the anomalies detected during this preparation,

and a stage for imputting post-reinjection follow-up information and forwarding said information to said operational entity.

Claim 16 (amended) System for processing information used for quality management in a therapeutic process involving several entities, optionally remote including an operational entity and a preparation laboratory, this therapeutic process comprising operations of taking cells from a patient, specific treatment operations on these cells using a specific treatment protocol, and a reinjection operation into the patient of said cells treated in tis way, these operations of taking cells, treatment and reinjection being subjected to a standard operating procedure for preparation (SOP) comprising a series of functional stages,

characterized in that it comprises, for each batch of samples taken from a given patient:

-for each functional stage, a means of sequential and conditional validation of said stage, passing from one validation stage to a following validation stage being conditional on results of processing of data collected during this validation stage and on a full completion by an operator of critical points within a screen page associated with said functional stage, [and]

-means for processing information and data collected in the different validation stages, said collected data being associated with said batch of samples and being indicative in particular of operators and of the process state of progress, in order to issue final certification of a preparation carried out according to the standard operating procedure and/or a list of the anomalies detected during this preparation, and

-means for imputting post-reinjection follow-up information and forwarding said information to said operational entity.